

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

VIVIAN D. COBB,
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE L.L.C., and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-00257-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE, LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company¹) ("Pharmacia")
3 and G.D. Searle LLC ("Searle") and file this Answer to Plaintiff's Complaint ("Complaint"),
4 and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
8 Celebrex® (celocoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally.
9 Defendants may seek leave to amend this Answer when discovery reveals the specific time
10 periods in which Plaintiff was prescribed and used Celebrex®.

11 **II.**

12 **ORIGINAL ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
15 deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or
16 information sufficient to form a belief as to the truth of the allegations in this paragraph of the
17 Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same.
18 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
19 damages, and deny the remaining allegations in this paragraph of the Complaint.

20 2. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age or state of
22 residence and, therefore, deny the same.

23 3. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of

24 _____
25 ¹ Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity
26 known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31,
27 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company,
28 Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag
Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed
Celebrex®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing
Celebrex®, see PLAINTIFF'S COMPLAINT at ¶ 7, Defendants assume Plaintiff means to refer to 1933 Monsanto. As
a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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1 Minnesota. Defendants state that the remaining allegations in this paragraph of the Complaint
2 assert legal contentions to which no response is required. To the extent that a response is
3 deemed required, Defendants deny the remaining allegations in this paragraph of the Complaint.

4 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of
5 business in New York. Defendants admit that Pfizer is registered to do business in the State of
6 Minnesota. Defendants admit that Pfizer may be served through its registered agent.
7 Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in
8 April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during
9 certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the
10 United States, including Minnesota, to be prescribed by healthcare providers who are by law
11 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
12 that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
13 Defendants are without knowledge or information to form a belief as to the truth of such
14 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this
15 paragraph of the Complaint.

16 5. Defendants admit that Searle is a Delaware limited liability company with its principal
17 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
18 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
19 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
20 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
21 Celebrex® in the United States to be prescribed by healthcare providers who are by law
22 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
23 the remaining allegations in this paragraph of the Complaint.

24 6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
25 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
26 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
27 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
28 Celebrex® in the United States to be prescribed by healthcare providers who are by law

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1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
2 the remaining allegations in this paragraph of the Complaint.

3 7. Defendants admit that in 1933 an entity known as Monsanto Company (“1933
4 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
5 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name
6 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,
7 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company
8 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged
9 in the agricultural business and does not and has not ever manufactured, marketed, sold, or
10 distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle
11 or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold,
12 or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper
13 party in this matter. Defendants deny the remaining allegations in this paragraph of the
14 Complaint. Defendants state that the response to this paragraph of the Complaint regarding
15 Monsanto is incorporated by reference into Defendants’ responses to each and every paragraph
16 of the Complaint referring to Monsanto and/or Defendants.

17 8. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
18 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
19 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
20 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
22 Celebrex® in the United States to be prescribed by healthcare providers who are by law
23 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
24 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle
25 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
28 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who

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1 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
2 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
3 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
6 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
7 prescribing information. Defendants state that the potential effects of Celebrex® were and are
8 adequately described in its FDA-approved prescribing information, which was at all times
9 adequate and comported with applicable standards of care and law. Defendants deny any
10 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

11 10. Defendants state that the allegations in this paragraph of the Complaint regarding
12 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
13 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
14 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 11. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of
16 Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 12. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of
18 Minnesota. Defendants are without knowledge sufficient to form a belief as to the allegations in
19 this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the
20 same. However, Defendants admit that Plaintiff claims the amount in controversy satisfies the
21 jurisdictional amount of this Court. Defendants deny the remaining allegations in this
22 paragraph of the Complaint.

23 **Response to Factual Allegations**

24 13. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical
26 condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state
27 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
28 prescribing information. Defendants state that the potential effects of Celebrex® were and are

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1 adequately described in its FDA-approved prescribing information, which was at all times
2 adequate and comported with applicable standards of care and law. Defendants deny that
3 Celebrex® caused Plaintiff injury or damages and deny the remaining allegations in this
4 paragraph of the Complaint.

5 14. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
12 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
13 paragraph of the Complaint.

14 15. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
17 Celebrex® was expected to reach users and consumers without substantial change from the time
18 of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 16. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 17. Defendants state that the allegations in this paragraph of the Complaint regarding
28 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response

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1 is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to
2 as being a non-steroidal anti-inflammatory (“NSAID”) drugs. Defendants deny the remaining
3 allegations in this paragraph of the Complaint.

4 18. Defendants state that the allegations in this paragraph of the Complaint are not directed
5 toward Defendants and, therefore, no response is required. To the extent that a response is
6 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
7 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
8 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

9 19. Defendants state that the allegations in this paragraph of the Complaint are not directed
10 toward Defendants and, therefore, no response is required. To the extent that a response is
11 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
12 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
13 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

14 20. Defendants state that the allegations in this paragraph of the Complaint are not directed
15 toward Defendants and, therefore, no response is required. To the extent that a response is
16 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
17 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
18 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19 21. Defendants state that the allegations in this paragraph of the Complaint are not directed
20 toward Defendants and, therefore, no response is required. To the extent a response is deemed
21 required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
22 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
23 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
24 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to
25 provide the proper context for the remaining allegations in this paragraph and Defendants
26 therefore lack sufficient information or knowledge to form a belief as to the truth of the
27 allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

28 22. Defendants state that the allegations in this paragraph of the Complaint regarding

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1 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
2 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
3 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
4 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
5 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
6 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants
7 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
8 approved prescribing information. Defendants state that the potential effects of Celebrex® were
9 and are adequately described in its FDA-approved prescribing information, which was at all
10 times adequate and comported with applicable standards of care and law. Defendants deny any
11 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

12 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
13 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
14 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
15 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
16 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
17 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
18 (“FAP”) as an adjunct to usual care (e.g., endoscopic surveillance surgery). Defendants deny
19 the remaining allegations in this paragraph of the Complaint.

20 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
21 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex®
22 in the United States to be prescribed by healthcare providers who are by law authorized to
23 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
24 certain periods of time, Celebrex® was manufactured and packaged for Searle, which
25 developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be
26 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
27 with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective
28 when used in accordance with its FDA-approved prescribing information. Defendants state that

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1 the potential effects of Celebrex® were and are adequately described in its FDA-approved
2 prescribing information, which was at all times adequate and comported with applicable
3 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
4 allegations in this paragraph of the Complaint.

5 25. Defendants state that the referenced article speaks for itself and respectfully refer the
6 Court to the article for its actual language and text. Any attempt to characterize the article is
7 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 26. Defendants state that the referenced article speaks for itself and respectfully refer the
9 Court to the article for its actual language and text. Any attempt to characterize the article is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 27. Defendants state that the referenced FDA Update speaks for itself and respectfully refer
12 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
13 FDA Update is denied. Defendants deny the remaining allegations in this paragraph of the
14 Complaint.

15 28. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny the allegations in this paragraph of the Complaint.

20 29. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on
27 June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
28 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,

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2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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36. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Plaintiff fails to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiff fails to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 43. Defendants admit that there was a clinical trial called APC. Defendants state that the
3 referenced article speaks for itself and respectfully refer the Court to the article for its actual
4 language and text. Any attempt to characterize the article is denied. Defendants deny the
5 remaining allegations in this paragraph of the Complaint.

6 44. Defendants state that the referenced article speaks for itself and respectfully refer the
7 Court to the article for its actual language and text. Any attempt to characterize the article is
8 denied. Plaintiff fails to provide the proper context for the allegations concerning “Data Safety
9 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
10 information or knowledge to form a belief as to the truth of such allegations and, therefore, deny
11 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 45. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 46. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
16 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
17 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 47. Defendants state that the referenced Medical Officer Review speaks for itself and
20 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
21 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
22 allegations in this paragraph of the Complaint.

23 48. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
24 the proper context for the allegations concerning “other Celebrex trials” contained in this
25 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
26 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
27 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that
28 the referenced study speaks for itself and respectfully refer the Court to the study for its actual

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1 language and text. Any attempt to characterize the study is denied. Defendants deny the
2 remaining allegations in this paragraph of the Complaint.

3 49. Defendants state that the referenced article speaks for itself and respectfully refer the
4 Court to the article for its actual language and text. Any attempt to characterize the article is
5 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

6 50. Plaintiff fails to provide the proper context for the allegations regarding Merck and
7 Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or
8 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
9 Defendants state that the referenced studies speak for themselves and respectfully refer the
10 Court to the studies for their actual language and text. Any attempt to characterize the studies is
11 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 51. Defendants state that the referenced Medical Officer Review speaks for itself and
13 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
14 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 52. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
17 are not directed toward Defendants, and therefore no response is required. To the extent that a
18 response is deemed required, Plaintiff fails to provide the proper context for the allegations
19 regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient
20 information or knowledge to form a belief as to the truth of such allegations and, therefore, deny
21 the same. Defendants state that the referenced study speaks for itself and respectfully refer the
22 Court to the study for its actual language and text. Any attempt to characterize the study is
23 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
25 Complaint are not directed toward Defendants, and therefore no response is required. To the
26 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
27 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
28 therefore lack sufficient information or knowledge to form a belief as to the truth of such

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1 allegations and, therefore, deny the same. Defendants state that the referenced study speaks for
2 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
3 to characterize the study is denied. Defendants deny the remaining allegations in this paragraph
4 of the Complaint.

5 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
6 Complaint are not directed toward Defendants, and therefore no response is required. To the
7 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
8 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
9 therefore lack sufficient information or knowledge to form a belief as to the truth of such
10 allegations and, therefore, deny the same. Defendants state that the referenced study speaks for
11 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
12 to characterize the study is denied. Defendants state that the referenced article speaks for itself
13 and respectfully refer the Court to the article for its actual language and text. Any attempt to
14 characterize the article is denied. Defendants deny the remaining allegations in this paragraph
15 of the Complaint.

16 55. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants deny the allegations in this
18 paragraph of the Complaint.

19 56. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 57. Defendants state that allegations in this paragraph of the Complaint are not directed
23 toward Defendants, and therefore no response is required. To the extent that a response is
24 deemed required, Defendants state that the referenced article speaks for itself and respectfully
25 refer the Court to the article for its actual language and text. Any attempt to characterize the
26 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 58. Defendants deny the allegations in this paragraph of the Complaint.

28 59. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
5 remaining allegations contained in this paragraph of the Complaint.

6 60. Defendants deny any wrongful conduct and deny the remaining allegations contained in
7 this paragraph of the Complaint.

8 61. Defendants deny any wrongful conduct and deny the remaining allegations contained in
9 this paragraph of the Complaint.

10 62. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
15 paragraph of the Complaint.

16 63. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
23 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
24 the Complaint.

25 64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
26 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
27 November 14, 2000. Defendants state that the referenced letters speak for themselves and
28 respectfully refer the Court to the letters for their actual language and text. Any attempt to

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1 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph
2 of the Complaint.

3 65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
4 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the
5 letter for its actual language and text. Any attempt to characterize the letter is denied.
6 Defendants deny the remaining allegations in this paragraph of the Complaint.

7 66. Defendants state that the referenced article speaks for itself and respectfully refer the
8 Court to the article for its actual language and text. Any attempt to characterize the article is
9 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

10 67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
11 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the
12 letter for its actual language and text. Any attempt to characterize the letter is denied.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 68. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
19 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
20 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
22 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
23 United States to be prescribed by healthcare providers who are by law authorized to prescribe
24 drugs in accordance with their approval by the FDA. Defendants deny the remaining
25 allegations in this paragraph of the Complaint.

26 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
3 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
4 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
6 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
7 United States to be prescribed by healthcare providers who are by law authorized to prescribe
8 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
9 prescription medication which is approved by the FDA for the following indications: (1) for
10 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
11 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
12 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
13 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
14 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
15 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
16 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
17 paragraph of the Complaint.

18 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which at all times was adequate and comported with applicable standards of care and law.
22 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
23 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
24 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
25 that Celebrex® is defective, and deny the remaining allegations in this paragraph of the
26 Complaint.

27 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
4 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
5 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
6 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
7 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
8 United States to be prescribed by healthcare providers who are by law authorized to prescribe
9 drugs in accordance with their approval by the FDA. Defendants deny the remaining
10 allegations in this paragraph of the Complaint.

11 72. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which at all times was adequate and comported with applicable standards of care and law.
15 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
16 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
17 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
18 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
19 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
20 United States to be prescribed by healthcare providers who are by law authorized to prescribe
21 drugs in accordance with their approval by the FDA. Defendants deny the remaining
22 allegations in this paragraph of the Complaint.

23 73. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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1 74. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 75. Defendants deny the allegations in this paragraph of the Complaint.

8 76. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 77. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 78. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
23 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
24 paragraph of the Complaint.

25 79. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
2 remaining allegations in this paragraph of the Complaint.

3 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® are and were adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
8 the Complaint.

9 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® are and were adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants state that the referenced study speaks for itself and respectfully refer the Court to the
14 study for its actual language and text. Any attempt to characterize the study is denied.
15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
16 the Complaint.

17 82. Defendants deny any wrongful conduct and deny the remaining allegations in this
18 paragraph of the Complaint.

19 83. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® are and were adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 **Response to First Cause of Action: Negligence**

28 84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's

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1 Complaint as if fully set forth herein.

2 85. Defendants state that this paragraph of the Complaint contains legal contentions to
3 which no response is required. To the extent that a response is deemed required, Defendants
4 admit that they had duties as are imposed by law but deny having breached such duties.
5 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
6 FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 86. Defendants state that this paragraph of the Complaint contains legal contentions to
12 which no response is required. To the extent that a response is deemed required, Defendants
13 admit that they had duties as are imposed by law but denies having breached such duties.
14 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
15 FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
19 the Complaint.

20 87. Defendants state that this paragraph of the Complaint contains legal contentions to
21 which no response is required. To the extent that a response is deemed required, Defendants
22 admit that they had duties as are imposed by law but deny having breached such duties.
23 Defendants are without knowledge or information sufficient to form a belief as to the truth of
24 the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®,
25 and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective
26 when used in accordance with its FDA-approved prescribing information. Defendants state that
27 the potential effects of Celebrex® were and are adequately described in its FDA-approved
28 prescribing information, which was at all times adequate and comported with applicable

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standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

88. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the

1 remaining allegations in this paragraph of the Complaint.

2 92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 Answering the unnumbered paragraph following Paragraph 92 of the Complaint,
5 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to Second Cause of Action: Strict Liability**

8 93. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
9 Complaint as if fully set forth herein.

10 94. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
13 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
14 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
15 with their approval by the FDA. Defendants admit that, during certain periods of time,
16 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
17 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
18 providers who are by law authorized to prescribe drugs in accordance with their approval by the
19 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
20 consumers without substantial change from the time of sale. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 95. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 96. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably
4 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

5 97. Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably
10 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

11 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
16 remaining allegations in this paragraph of the Complaint.

17 99. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
22 remaining allegations in this paragraph of the Complaint.

23 100. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
2 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damages, and deny the
3 remaining allegations in this paragraph of the Complaint.

4 101. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 102. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
18 paragraph of the Complaint.

19 103. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 104. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint

5 105. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
8 damages, and deny the remaining allegations in this paragraph of the Complaint.

9 107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
10 damages, and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to Third Cause of Action: Breach of Express Warranty**

12 108. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
13 Complaint as if fully set forth herein.

14 109. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
21 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
22 Complaint.

23 110. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
2 information for Celebrex®. Defendants deny any wrongful conduct and deny the remaining
3 allegations in this paragraph of the Complaint, including all subparts.

4 111. Defendants admit to providing FDA-approved prescribing information for Celebrex®.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 112. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 113. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 114. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 115. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
27 damages, and deny the remaining allegations in this paragraph of the Complaint.

28 116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or

1 damages, and deny the remaining allegations in this paragraph of the Complaint.

2 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Fourth Cause of Action: Breach of Implied Warranty**

5 118. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
6 Complaint as if fully set forth herein.

7 119. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
14 the remaining allegations in this paragraph of the Complaint.

15 120. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
20 Defendants deny the remaining allegations in this paragraph of the Complaint.

21 121. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 122. Defendants state that this paragraph of the Complaint contains legal contentions to
27 which no response is required. To the extent that a response is deemed required, Defendants
28 state that Celebrex® was and is safe and effective when used in accordance with its FDA-

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1 approved prescribing information. Defendants state that the potential effects of Celebrex® were
2 and are adequately described in its FDA-approved prescribing information, which was at all
3 times adequate and comported with applicable standards of care and law. Defendants deny any
4 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

5 123. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
8 medication which is approved by the FDA for the following indications: (1) for relief of the
9 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
10 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
11 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
12 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
13 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
14 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 124. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
23 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
24 Complaint.

25 125. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
28 Celebrex® was expected to reach users and consumers without substantial change from the time

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1 of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 126. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
9 remaining allegations in this paragraph of the Complaint.

10 127. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
11 damages, and deny the remaining allegations in this paragraph of the Complaint.

12 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
13 damages, and deny the remaining allegations in this paragraph of the Complaint.

14 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
15 damages, and deny the remaining allegations in this paragraph of the Complaint.

16 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

17 130. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
18 Complaint as if fully set forth herein.

19 131. Defendants state that this paragraph of the Complaint contains legal contentions to
20 which no response is required. To the extent that a response is deemed required, Defendants
21 admit that they had duties as are imposed by law but deny having breached such duties.
22 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 132. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint, including all subparts.

6 133. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint, including all subparts.

12 134. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
19 remaining allegations in this paragraph of the Complaint, including all subparts.

20 135. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 136. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
5 remaining allegations in this paragraph of the Complaint.

6 137. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
13 remaining allegations in this paragraph of the Complaint.

14 138. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
21 remaining allegations in this paragraph of the Complaint.

22 139. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny any wrongful conduct and deny the

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1 remaining allegations in this paragraph of the Complaint.

2 140. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
9 remaining allegations in this paragraph of the Complaint.

10 141. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
19 damages, and deny the remaining allegations in this paragraph of the Complaint.

20 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
21 damages, and deny the remaining allegations in this paragraph of the Complaint.

22 144. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
23 damages, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Sixth Cause of Action: Unjust Enrichment**

25 145. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
26 Complaint as if fully set forth herein.

27 146. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
28 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who

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1 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
2 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
3 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
6 the remaining allegations in this paragraph of the Complaint.

7 147. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
10 paragraph of the Complaint.

11 148. Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
14 paragraph of the Complaint.

15 149. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 150. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
4 damages, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Prayer For Relief**

6 Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,”
7 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
8 damages, and deny the remaining allegations this paragraph of the Complaint, including all
9 subparts.

10 **III.**

11 **GENERAL DENIAL**

12 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s
13 Complaint that have not been previously admitted, denied, or explained.

14 **IV.**

15 **AFFIRMATIVE DEFENSES**

16 Defendants reserve the right to rely upon any of the following or additional defenses to
17 claims asserted by Plaintiff to the extent that such defenses are supported by information
18 developed through discovery or evidence at trial. Defendants affirmatively show that:

19 **First Defense**

20 1. The Complaint fails to state a claim upon which relief can be granted.

21 **Second Defense**

22 2. Celebrex® is a prescription medical product. The federal government has preempted
23 the field of law applicable to the labeling and warning of prescription medical products.
24 Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable
25 federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim
26 upon which relief can be granted; such claims, if allowed, would conflict with applicable
27 federal law and violate the Supremacy Clause of the United States Constitution.

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Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

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Tenth Defense

10. Any injuries or expenses incurred by Plaintiff was not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff was legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the

1 Complaint, the same were caused by the unforeseeable alteration, change, improper handling,
2 abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants
3 or persons acting on its behalf after the product left the control of Defendants.

4 **Seventeenth Defense**

5 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
6 Defendants.

7 **Eighteenth Defense**

8 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
9 conditions unrelated to Celebrex®.

10 **Nineteenth Defense**

11 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,
12 the doctrine of assumption of the risk bars or diminishes any recovery.

13 **Twentieth Defense**

14 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
15 preempted in accordance with the Supremacy Clause of the United States Constitution and by
16 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

17 **Twenty-first Defense**

18 21. Plaintiff's claims are barred in whole or in part under the applicable state law because
19 the subject pharmaceutical product at issue was subject to and received pre-market approval by
20 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

21 **Twenty-second Defense**

22 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
23 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
24 and Plaintiff's causes of action are preempted.

25 **Twenty-third Defense**

26 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary
27 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
28 issue under applicable federal laws, regulations, and rules.

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Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Minnesota, Ohio, and California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause

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of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota, Ohio, and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed,

1 tested, manufactured and labeled in accordance with the state-of-the-art industry standards
2 existing at the time of the sale.

3 **Forty-first Defense**

4 41. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information
5 and belief, such injuries and losses were caused by the actions of persons not having real or
6 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
7 no control and for whom Defendants may not be held accountable.

8 **Forty-second Defense**

9 42. The claims asserted in the Complaint are barred, in whole or in part, because
10 Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for
11 which it was intended, and was distributed with adequate and sufficient warnings.

12 **Forty-third Defense**

13 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
14 waiver, and/or estoppel.

15 **Forty-fourth Defense**

16 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the
17 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
18 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were
19 independent of or far removed from Defendants' conduct.

20 **Forty-fifth Defense**

21 45. The claims asserted in the Complaint are barred, in whole or in part, because
22 Celebrex® did not proximately cause injuries or damages to Plaintiff.

23 **Forty-sixth Defense**

24 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff
25 did not incur any ascertainable loss as a result of Defendants' conduct.

26 **Forty-seventh Defense**

27 47. The claims asserted in the Complaint are barred, in whole or in part, because the
28 manufacturing, labeling, packaging, and any advertising of the product complied with the

1 applicable codes, standards and regulations established, adopted, promulgated or approved by
2 any applicable regulatory body, including but not limited to the United States, any state, and
3 any agency thereof.

4 **Forty-eighth Defense**

5 48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if
6 the product labeling contained the information that Plaintiff contends should have been
7 provided.

8 **Forty-ninth Defense**

9 49. The claims asserted in the Complaint are barred because the utility of Celebrex®
10 outweighed its risks.

11 **Fiftieth Defense**

12 50. Plaintiff's damages, if any, are barred or limited by the payments received from
13 collateral sources.

14 **Fifty-first Defense**

15 51. Defendants' liability, if any, can only be determined after the percentages of
16 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
17 any, are determined. Defendants seek an adjudication of the percentage of fault of the
18 claimants and each and every other person whose fault could have contributed to the alleged
19 injuries and damages, if any, of Plaintiff.

20 **Fifty-second Defense**

21 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that
22 the common law gives deference to discretionary actions by the United States Food and Drug
23 Administration under the Federal Food, Drug, and Cosmetic Act.

24 **Fifty-third Defense**

25 53. The claims asserted in the Complaint are barred, in whole or in part, because
26 Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug &
27 Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under,
28 and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to

1 implement the FDCA, with the purposes and objectives of the FDCA and FDA's
2 implementing regulations, and with the specific determinations by FDA specifying the
3 language that should be used in the labeling accompanying Celebrex®. Accordingly,
4 Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution,
5 Article VI, clause 2, and the laws of the United States.

6 **Fifty-fourth Defense**

7 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
8 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

9 **Fifty-fifth Defense**

10 55. Defendants state on information and belief that the Complaint and each purported
11 cause of action contained therein is barred by the statutes of limitations contained in California
12 Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of
13 limitation as may apply.

14 **Fifty-sixth Defense**

15 56. Defendants state on information and belief that any injuries, losses, or damages
16 suffered by Plaintiff was proximately caused, in whole or in part, by the negligence or other
17 actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's
18 recovery against Defendants, if any, should be reduced pursuant to California Civil Code §
19 1431.2.

20 **Fifty-seventh Defense**

21 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
22 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
23 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
24 damages is also barred under California Civil Code § 3294(b).

25 **Fifty-eighth Defense**

26 58. Plaintiff's claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

27 **Fifty-ninth Defense**

28 59. Plaintiff's claims for punitive damages are barred, in whole or in part, by § 2315.21 of

the Ohio Revised Code and are subject to all provisions of the Ohio Revised Code.

Sixtieth Defense

60. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources and the provisions of the Ohio Revised Code.

Sixty-first Defense

61. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Ohio law.

Sixty-second Defense

62. Plaintiff's damages, if any, must be reduced by the percentage of fault attributable to Plaintiff and to nonparties as provided by the Ohio Revised Code.

Sixty-third Defense

63. One or more of Plaintiff's claims for damages are subject to statutory limits on certain types of damages, and the Court is without jurisdiction to enter judgment for Plaintiff beyond the limits set forth in the Ohio Revised Code.

Sixty-fourth Defense

64. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiff's claims, including the limits and restrictions on damages set forth herein.

Sixty-fifth Defense

65. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff takes nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability

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San Francisco, CA 94111

1 of all persons whose fault or other liability proximately caused Plaintiff's alleged
2 injuries, losses or damages is attributable to each person;

3 5. That any judgment for damages against Defendants in favor of Plaintiff be no greater
4 than an amount which equals their proportionate share, if any, of the total fault or other
5 liability which proximately caused Plaintiff's injuries and damages; and

6 6. That Defendants have such other and further relief as the Court deems appropriate.

7
8 May 30, 2008

GORDON & REES LLP

9
10 By: : _____/s/
11 Stuart M. Gordon
12 sgordon@gordonrees.com
13 Embarcadero Center West
14 275 Battery Street, 20th Floor
15 San Francisco, CA 94111
16 Telephone: (415) 986-5900
17 Fax: (415) 986-8054

18
19 May 30, 2008

TUCKER ELLIS & WEST LLP

20
21 By: : _____/s/
22 Michael C. Zellers
23 michael.zellers@tuckerellis.com
24 515 South Flower Street, Suite 4200
25 Los Angeles, CA 90071-2223
26 Telephone: (213) 430-3400
27 Fax: (213) 430-3409

28
Attorneys for Defendants
PFIZER INC., PHARMACIA
CORPORATION, AND G.D. SEARLE
LLC

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

May 30, 2008

GORDON & REES LLP

By: : _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

May 30, 2008

TUCKER ELLIS & WEST LLP

By: : _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC., PHARMACIA
CORPORATION, AND G.D. SEARLE
LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111